

## 90-DAY RESPONSE

**DCI Number: GDCI-043901-1668**

### Data Call-In Information

Company Name	SURETY LABORATORIES
Company Address	2 STEWART COURT DENVILLE, NJ 07834
DCI Type	Generic
Issued Date	09/21/2017
90 Day Response Deadline	12/30/2017
CRM Information	opp_ad_reevaluation_DCI_team@epa.gov
Chemical Name	Glutaraldehyde
Chemical Number	043901

### 90-Day Response Information

Tracking Number	CDX_DCI_2018_000075
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### DCI Level Documents

File Name	File Type	MRID	CBI	Submitted Date
SuretyLabs_GDCI_043901-1668_90 Day Response_Cover Letter.pdf	Submission Cover Letter	NA	N	01/10/2018
Surety_DataCallInResponseForm.pdf	Submission Cover Letter	NA	N	01/10/2018

### EPA Product Registration Number(s)

68868 2	I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.
Source EPA Registration Number(s)	

### Guideline Requirement Number(s)

#### Guideline Requirement Number - 850.4400

Study Title	Aquatic Plant Toxicity Using Lemna spp
Protocol	N
Target Submission Date	09/21/2018
Use Pattern	R; S; T; U; V; X; Z
Test Substance	TGA
Time Frame	12 month(s)
Footnote(s)	1. Based on the results of a previous study on green algae indicating the EC50 is less than 1 mg/l (1 ppm), tier II data on a vascular aquatic plant (850.4400; Lemna spp.), freshwater diatom (GLN 850.4500; Navicula pelliculosa), and marine diatom (GLN 850.4500; Skeletonema costatum) are required.
Registrant Response	NA

#### Guideline Requirement Number - 850.4500

Study Title	Algal Toxicity
Protocol	N
Target Submission Date	09/21/2018
Use Pattern	R; S; T; U; V; X; Z
Test Substance	TGA
Time Frame	12 month(s)

\*Product ingredient source information may be entitled to confidential treatment\*

Footnote(s)	<p>1. Based on the results of a previous study on green algae indicating the EC50 is less than 1 mg/l (1 ppm), tier II data on a vascular aquatic plant (850.4400; Lemna spp.), freshwater diatom (GLN 850.4500; Navicula pelliculosa), and marine diatom (GLN 850.4500; Skeletonema costatum) are required.</p> <p>3. Green algae study not required, since EPA has in-house study MRID 45609401. Fresh Water Algal Growth Inhibition Test with Glutaraldehyde 50% M.H.J. Migchielsen, 2001.</p> <p>4. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See Final Test Guidelines; OCSPP 850 Series; Notice of Availability 77 FR 38282, June 27, 2012. <a href="https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028">https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028</a>.</p>
Reg strant Response	NA
<b>Guideline Requirement Number - 875.1400</b>	
Study T t e	Inhalation exposure--indoor
Protoco	Y
Target Subm ss on Date	09/21/2019
Use Pattern	R; S; T; U; V; X; Z
Test Substance	TGAI
T me Frame	24 month(s)
Footnote(s)	<p>5. Inhalation exposure scenarios for handlers (875.1400) include: open pour application; paint application; machinist trigger spray and wipe application for medical premises disinfection; spray, mop, and sponge application for agricultural, commercial, and food processing premises disinfection; and mop, wipe, and trigger spray application of preserved cleaning products. Inhalation exposure scenarios for post-application (875.2500) include: painting; hard surface disinfection; laundry detergent; and metal working fluids. For similar scenarios, results of 875.2500 may be used to estimate exposures and satisfy the data requirements for 875.1400.</p> <p>6. Protocols must be approved by the Agency prior to the initiation of the study.</p>
Reg strant Response	NA
<b>Guideline Requirement Number - 875.2500</b>	
Study T t e	Inhalation exposure
Protoco	Y
Target Subm ss on Date	09/21/2019
Use Pattern	R; S; T; U; V; X; Z
Test Substance	TGAI
T me Frame	24 month(s)
Footnote(s)	<p>5. Inhalation exposure scenarios for handlers (875.1400) include: open pour application; paint application; machinist trigger spray and wipe application for medical premises disinfection; spray, mop, and sponge application for agricultural, commercial, and food processing premises disinfection; and mop, wipe, and trigger spray application of preserved cleaning products. Inhalation exposure scenarios for post-application (875.2500) include: painting; hard surface disinfection; laundry detergent; and metal working fluids. For similar scenarios, results of 875.2500 may be used to estimate exposures and satisfy the data requirements for 875.1400.</p> <p>6. Protocols must be approved by the Agency prior to the initiation of the study.</p>
Reg strant Response	NA
<b>Guideline Requirement Number - SS-Migration</b>	
Study T t e	Migration studies
Protoco	Y
Target Subm ss on Date	09/21/2018
Use Pattern	R; S; T; U; V; X; Z
Test Substance	TGAI
T me Frame	12 month(s)
Footnote(s)	<p>2. For the three highlighted scenarios (i.e., commercial assessment, paper manufacturing, and food processing plants) the residue screening level default at 100% of the application rate triggered a risk of concern (see Section 3.2.1); and therefore, a migration study is required to refine the potential exposures. If the surface residues measured after a potable water rinse (PWR) no longer trigger a risk concern no additional migration data are needed. However, if the measured surface residues with a PWR still trigger a risk concern, then a second tier migration study measuring the transfer of residues from surfaces to food items is needed.</p> <p>6. Protocols must be approved by the Agency prior to the initiation of the study.</p>

Reg strant Response	NA
<b>Submitter Information</b>	
Subm tter	Georgia Anastasiou
Subm tted Date	01/10/2018